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Kevin P. Baker

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BRINKS, HOFER, GILSON & LIONE
PO BOX 10395
Chicago, IL 60611-5599

EXAMINER

VOGEL, NANCY S

ART UNIT

PAPER NUMBER

1636

MAIL DATE

DELIVERY MODE

03/24/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

DETAILED ACTION

Claims 27-41 are pending in the case.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 27-41 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

This rejection is maintained essentially for the reasons made of record in the previous Office action, mailed 9/19/07

Applicant's arguments, filed 12/27/07 have been considered but have not been found convincing.

Applicants have argued that other patents assigned to Genentech, sharing similar specifications, and having examples disclosing results in an MLR assay to demonstrate utility and enablement. However, it is noted that the prosecution history of US Patent 7,220,835, for instance, differs from the instant application's history, in that a Declaration that "provides support for the assertion that the claimed protein decreases the response of the MLR, demonstrating immunosuppression in vitro", was submitted,

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leading to the withdrawal of a rejection made under 35 USC 112 p1, enablement.

Further, claims in 7,220,835, were not drawn to nucleic acids that hybridize to the disclosed nucleic acids. Therefore, the fact that patents have issued to nucleic acids whose use and enablement is based on the MLR assay, is not sufficient to provide convincing arguments for the withdrawal of the rejections in the instant case.

Furthermore, applicants argue that each of the references cited in the previous Office action regarding the MLR assay, i.e. Kahan, Piccotti et al, Campo et al., are not convincing in support of a lack of enablement for the claimed nucleic acids encoding the polypeptide shown in SEQ ID NO:83. Applicant argues that the references are inconsistent with what was known and accepted in the art at the time of filing regarding the MLR assay, and cites US Patent 5,817,306, which contains a sentence attesting to the value of the MLR and PHA assays for “identifying immune suppressive molecules in vitro that are useful for treating graft versus host disease” , US Patent 5,801,193, which states that “MLR is an assay recognized by those skilled in the art as an in vitro predictor of in vivo immunosuppressant activity”, and US Patent 5,648,376 that states “a measure of immunosuppressive that serves as a model for transplantation rejection is inhibitor of cell proliferation in a ...(MLR) assay”, (page 7). However, it was previously argued that while the MLR assay may be taken as a general indicator of possible function in vivo, there is not sufficient guidance for the actual therapeutic use of the claimed nucleic acid or the polypeptide it encodes. The results of the MLR assay are merely preliminary, and further research is necessary for on to use the claimed invention in the manner disclosed. Further, applicant argues that Campo et al.

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"supports Applicants' position that those of skill in the art would interpret the results of MLC assays as having physiological relevance"; however, it remains that Campo et al. found that there are difficulties in applying in vitro assay results to the in vivo therapeutic use of a particular compound. Applicants further state that the cited references actually state that the MLR is an important method with a good predictive value. However, it is maintained that the sections of the cited references remain relevant, and provide support for the argument that the claims are not fully enabled since the MLR assay is only generally predictive, but the extensive further research would be required to practice and use the invention claimed. The citation of Vogel was made in order to provide further support for the lack of predictable correlation between in vitro and in vivo therapeutic results, and it is maintained that this reference was properly cited.

Applicants have stated that the amendments to the claims to recite that the nucleic acids recited in claims 35-37, ie those that hybridize to the nucleic acid encoding SEQ ID NO:83 and "also inhibits suppression of an immune response in a MLR assay" , suffices to overcome the rejection of these claims for lack of enablement. However, these claims remain rejected, since there is no enablement provided in the specification for the use of nucleic acids hybridizing to the nucleic acid which encodes the polypeptide of SEQ ID NO:83 as inhibitors of suppression of an immune response in a MLR assay. It is noted that if the claims had recited that the nucleic acids claimed were those that hybridized under the recited conditions to those that encode the polypeptide of SEQ ID NO:83, and which encode a polypeptide that inhibits suppression of an

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immune response in a MLR assay, they would be rejected for the reasons set forth above and stated in the previous Office action.

The following is a new rejection necessitated by applicant's amendments to the claims:

Claims 35-37 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The specification as originally filed does not provide support for the invention as now claimed: "wherein said isolated nucleic acid inhibits proliferation of stimulated T-cells in a mixed lymphocyte reaction assay", since the specification does not disclose that the claimed nucleic acids inhibit proliferation of stimulated T-cells in a mixed lymphocyte reaction assay. This a new matter rejection. The specification does not provide sufficient blazemarks nor direction for the instant methods encompassing the above-mentioned limitations, as currently recited. The instant claims now recite limitations which were not clearly disclosed in the specification as-filed, and now change the scope of the instant disclosure as-filed. Such limitations recited in the present claims, which did not appear in the specification, as filed, introduce new concepts and violate the description requirement of the first paragraph of 35 U.S.C. 112.

Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to NANCY VOGEL whose telephone number is (571)272-0780. The examiner can normally be reached on 7:00 - 3:30, Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach can be reached on (571) 272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/NANCY VOGEL/
Primary Examiner, Art Unit 1636

NV
3/13/08